ATS Statement—Snowbird Workshop on Standardization of Spirometry

AMERICAN THORACIC SOCIETY, medical section of American Lung Association

THIS IS AN OFFICIAL STATEMENT OF ATS ADOPTED BY COUNCIL, MAY 1979

Chairman's Comment

The following report is a result of considerable effort and thought. In June 1976, the Medical Devices Committee of the American Thoracic Society prepared a rough draft of proposed standards for spirometry. As a follow-up to this, funds were obtained from ATS, National Heart Lung and Blood Institute Contract No. 1-HR-5-3028 (Standardization in Epidemiological Studies), and a workshop was scheduled with the cooperation and participation of Dr. Hans Weill, then president of ATS. The following recommendations are the outcome of the two-day workshop (January 18–19, 1977) held at Snowbird, Utah. Since then, there has been feedback from workshops members and input from manufacturers and users after presentation of material at the ATS Annual Meeting in May 1977 and the ATS News in the summer of 1977. The document was circulated to the Snowbird workshop members in April 1978 and presented to the ATS Council at its annual meeting in Boston in May 1978. Following this meeting, changes were made and workshop members were polled for approval. The workshop had representation from clinical and the epidemiologic areas. Since the document was approved by consensus of the 22 scientists present, these standards are proposed for clinical and epidemiologic studies.

The instrument specifications are *minimum recommendations*. Any manufacturer making an instrument should at least meet these specifications. However, there are several specifications where improvements would be desirable and welcomed.

The instrument specifications are summarized in table 1. Each pulmonary function test is listed individually so it can be applied to devices independently. It is not necessary for a "spirometer" to perform all of the tests. For example, an instrument may only be appropriate for measuring VC; therefore, it would only be required to meet the VC standard.

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Spirometers need not perform all tests, but the tests they are advertised to measure should meet the following as a minimum. Definitions are taken from a report of the ACCP-ATS Joint Committee on Pulmonary Nomenclature (1).

Test Title

Vital Capacity (VC)

Definition

The maximal volume of air exhaled from the point of maximal inspiration.

Standard

If an instrument claims to measure VC, it should continue to accumulate volume for at least 30 sec. The instrument should be capable of measuring volumes of at least 7 liter (BTPS) independent of flow rate for flows between 0 and 12 liter per sec. Accuracy required is at least ± 3 per cent of reading or ± 50 ml, whichever is greater.

TABLE 1

MINIMAL SPIROMETRY STANDARDS SUMMARY

Test	Range/Accuracy BTPS (liter)	Flow Range (liter/sec)	Time (sec)	Start Point	Resistance and Back Pressure	Test Signals
VC	7 liter/± 3% of reading or 50 ml, whichever is greater	0→ 12	30	–		Calibrated Syringe
FVC	7 liter/± 3% of reading or 50 ml, whichever is greater	0→ 12	10.0	–		2 simulated FVC signals in range (1) FVC = 5 liter τ = 0.4 sec (2) FVC = liter τ = 2.4 sec
FEV_t	7 liter/± 3% of reading	0→ 12	t	Back extrapolate or equivalent	Less than 1.5 cm H_2O liter/sec at 12.0 liter/sec flow	Same as FVC
FEV_1			1.0			
FEF 25–75%	7 liter/± 5% of reading or 0.1 liter/sec, whichever is greater	0→ 12	10.0	–	Same as FEV_t	Same as FVC
$\dot{V}$	12 liter/sec/± 5% of reading or 0.2 liter/sec, whichever is greater	0→ 12	10.0	–	Same as FEV_t	Manufacturer proof
MVV	Sine wave 250 liter/min @ 2 liter to ± 5% of reading	0→12 ± 5%	12–15 ± 3%	–	Pressure less than ± 10 cm H_2O @ 2 liter TV 2.0 Hz	Sine wave pump 0→ 4 Hz ± 10% @ ± 12 liter/sec

APPENDIX A

HANKINSON, J.L., AND PETERSEN, M.R.: DATA ANALYSIS FOR SPIROMETRY INSTRUMENTATION STANDARDS (ABSTRACT), AM REV RESPIR DIS, 1977, *115* (SUPPLEMENT, p. 116)

TABLE 1

OCCURRENCES OF FVC

Range	Number	Percentage
FVC ⩽ 5.25	5,835	.62.43%
5.25 < FVC ⩽ 5.75	1,732	18.53%
5.75 < FVC ⩽ 6.25	1,035	11.07%
6.25 < FVC ⩽ 6.75	491	5.25%
6.75 < FVC ⩽ 7.25	184	1.97%
7.25 < FVC ⩽ 7.75	66	0.71%
7.75 < FVC	4	0.04%
Total	9,347	100.00%

TABLE 2

OCCURRENCES OF PEAK FLOW

Range	Number	Percentage
PKF ⩽ 10.25	7,105	76.01%
10.25 < PKF ⩽ 10.75	611	6.54%
10.75 < PKF ⩽ 11.25	485	5.19%
11.25 < PKF ⩽ 11.75	358	3.83%
11.75 < PKF ⩽ 12.25	279	2.99%
12.25 < PKF ⩽ 12.75	191	2.04%
12.75 < PKF ⩽ 13.25	147	1.57%
13.25 < PKF ⩽ 13.75	100	1.07%
13.75 < PKF ⩽ 14.25	37	0.40%
142.5 < PKF	34	0.36%
Total	9,347	100.00%

Rationale

Based on Hankinson and Petersen's data (Tables 1–4 Appendix A) (2) on 9,347 working coal miners, the range for volume and flow were established. Ninety-seven per cent of the miners had a forced vital capacity of less than 7.25 liter and 97 per cent had a peak flow of less than 13.25 liter per sec. If the spirometer is used for inspiration and expiration, a volume capacity of greater than 7 liter will be necessary. The volume requirement of 7 liter also applies to children. The work of Dickman and associates (3), Schmidt and co-workers (4), and Knudson and associates (5) demonstrate this need. In addition, there was concurrence of workshop participants representing pediatric interests. Older men and women have volumes similar to those of children (3–5). A 7-liter spirometer will not measure the person with "super" lungs, but it will cover the majority of the population. Accuracy of ± 3 per cent of reading or ± 50 ml, whichever is greater, is based on the data of Hankinson and Petersen (2). Their data showed coefficient of variation on the same subject on different days of 3 per cent or less. (Table 3 Appendix A) These data have been substantiated by Glindmeyer and others (6, 25). The instruments must be capable of measuring flows in the range of 0 to 12 liter per sec. The 12 liter per sec maximal flow rate selection was determined from Hankinson and Petersen's data (2), which show that less than 4.5 per cent of the population have flow rates greater than 12 liter per sec. (table 2, Appendix A) The volume accuracy is required on either flow or volume measuring instruments to be ± 3 per cent of reading or ± 50 ml, whichever is greater.

TABLE 3

VARIABILITY OF FVC, FEV_1, FEF_{50} FOR MULTIPLE TESTS ON THE SAME SUBJECT OVER A 1 TO 2 YEAR PERIOD

	Mean	Standard Error of the Estimate	Coefficient of Variation	N	Total
		FVC			
Males	5.45	0.116	2.13%	13	150
Females	3.89	0.117	3.00%	7	81
		FEV_1			
Males	4.28	0.099	2.31%	13	150
Females	3.40	0.125	3.68%	7	81
		FEF_{50}			
Males	4.43	0.109	4.72%	13	111
Females	4.26	0.336	7.89%	5	48

TABLE 4

EXPIRATORY TIME IN SECONDS (FETX%)
TOTAL POPULATION N = 1,222 COAL MINERS

	FET90%	FET95%	FET100%
Mean	2.29	3.61	6.87
Standard Deviation	1.39	2.13	3.72
Subjects with Obstruction ($FEV_1/FVC < 70\%$) N = 205			
	FET90%	FET95%	FET100%
Mean	4.45	6.50	10.21
Standard Deviation	1.76	2.57	4.24

Test Signal

The test signal for VC will be a calibrated syringe with a volume of at least 3 liter or a suitably calibrated spirometer tested over the volume range of the instrument.

Test Title

Forced Vital Capacity (FVC)

Definition

Vital capacity performed with a maximally forced expiratory effort.

Standard

The spirometer should be capable of measuring volumes up to at least 7 liter (BTPS) independent of flow rate for flows between 0 and 12 liter per sec. The instrument should be capable of accumulating volume for at least 10 sec. The instrument should accumulate all of the expired volume for at least ± 3 per cent of reading or ± 50 ml, whichever is greater. The volume accuracy requirement is the primary determinant of the flow accuracy. "End of test" will occur when the average flow over a 0.5-second interval is less than 50 ml per sec or when the volume change in a 0.5-second interval is less than 25 ml.

Rationale

For the FVC test, the volume and flow requirements are the same as for the VC (2–6). Hankinson and Petersen (2) have shown that FVC maneuvers must be recorded for at least 10 sec if 94 per cent of 205 subjects with obstructive lung disease are to be correctly classified (table 4, Appendix A). (Airway obstruction is defined as FEV_1/FVC ratio less than 70 per cent.)

Test Signal

The FVC will be simulated by "exponential" volume-time curves. The first simulated exhalation will have an FVC of 5 liter and a time constant of 0.4 sec (peak flow, 12.5 liter per sec). The second will have an FVC of 3.5 liter and a time constant of 2.4 sec (peak flow, 1.46 liter per sec).

Test Title

Timed Forced Expiratory Volume (FEV_t)

Definition

The volume of air exhaled in the specified time during the performance of the FVC, e.g., FEV_1 for the volume of air exhaled during the first sec of FVC.

Standard

The FEV_t will require a spirometer having a volume of at least 7 liter and a volume accuracy of at least ± 3 per cent of reading or ± 50 ml, whichever is greater over the flow range of 0 to 12 liter per sec. The instrument should measure the FEV_1 within an accuracy of at least ± 3 per cent of reading or ± 50 ml, whichever is greater. Because most instruments will also measure FVC and FEV_1/FVC ratios, they should be capable of accumulating volume for at least 10 sec. The "start of test" for purposes of timing will be determined by the back extrapolation method (7, 8) or a method shown to be equivalent. The resistance to air flow at 12.0 liter per sec should be less than 1.5 cm H_2O per liter per sec.

Rationale

FEV_t measurement is influenced by the point selected as the start of the test. A uniform method of selecting the point is required to maintain consistency. The back extrapolation (7, 8) method is the most consistent and accepted method (see section on measurement standardization which follows) and should be used until other methods are demonstrated to give equivalent results. Flow resistance is important in determining the FEV_1 and other timed expirations (9–14).

Test Signal

The test signal for FEV_t is the same as that used for FVC.

Test Title

Mean Forced Expiratory Flow during the middle half of the FVC ($FEF_{25-75\%}$)

Definition

Self-explanatory. Formerly called the maximal mid-expiratory flow rate (MMEF).

Standard

The $FEF_{25-75\%}$ should be measured on a system with at least a 7-liter capacity with flow in the range of 0 to 12 liter per sec and the capability of recording volume for at least 10 sec. The $FEF_{25-75\%}$ has an accuracy requirement of ± 5 per cent of reading or ± 100 ml per sec, whichever is greater.

Rationale

This test result has a much larger patient standard deviation from FVC or FEV_1 because 2 measurements of volume and time are required.

Test Signal

The test signal for $FEF_{25-75\%}$ is the same as that used for FVC and FEV_1.

Test Title

Flow ($\dot{V}$)

Definition

Instantaneous forced expiratory flow.

Standard

Flow may be measured electronically or graphically. Where flow-volume loops or other uses of flow are made, with flow in the range of 0 to 12 liter per sec, the flow should be within ± 5 per cent of reading or ± 0.2 liter per sec, whichever is greater. The time interval available for the test should be at least 10 sec.

Rationale

Flow signals are sometimes the primary signal used to make volume measurements (by integration). They are usually less accurate than volume measurements and are much more difficult to calibrate. Other instruments differentiate volume signals to get flow. With the "noise," phase-shift, and associated problems, flows accurate to within ± 5 per cent were believed to be adequate. Whenever a flow transducer is integrated to measure volume, it is the volume requirement that should be accurate to within ± 3 per cent of reading or 50 ml, whichever is greater.

Test Signal

"Exponential" signals specified for the FVC and FEV_1 testing are the suggested signals. Proof of the qualification of the instrument to this standard will require proof by the manufacturer until standard testing procedures can be designed. Instruments having $\dot{V}$ capability will require the instrument to be so labeled.

Test Title

Maximal Voluntary Ventilation (MVV)

Definition

The volume of air expired in a specified period during repetitive maximal respiratory effort.

Standard

When a spirometer is used for measuring MVV it should have a response that is flat within ± 10 per cent up to 4 Hz at flow rates of up to 12 liters per sec over the volume range. (See Test Signal and table 1.) The time for exhaled volume integration or recording should be no less than 12 or more than 15 sec. The indicated time should be accurate to within ± 3 per cent.

Rationale

For the MVV maneuver, the frequency content of the volume-time signal is high (15, 16) and, therefore, results are instrument dependent (17–19). The listed references give the rationale for this standard.

Test Signal

When tested with a pump producing a sinusoidal waveform, the indicated response of the instrument in incrementally increased flow up to 250 liter per min signal, produced with stroke volumes up to 2 liter, should be accurate within ± 5 per cent of reading. During the testing the pressure at the mouthpiece should not exceed ± 10 cm H_2O. For volume spirometers these requirements apply throughout the volume range.

Recorders

Diagnostic spirometry requires a graphic recording. In only two applications recorders are not required but are highly recommended. (*1*) For screening purposes; if the screening spirometry is abnormal, a recorded diagnostic spirometry should be made. (*2*) For follow-up studies requiring limited information for patients who have already had a diagnostic spirometry. In these applications it is permissible to use devices that meet the minimal requirements specified previously but do not produce a hard copy graphic record.

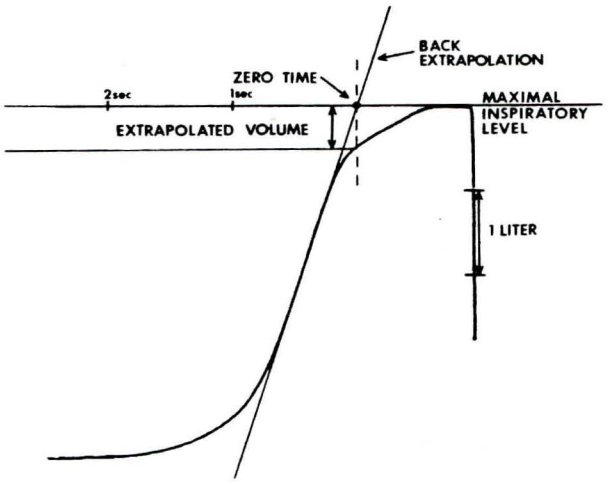

Fig. 1. Extrapolated volume.

Recorder Requirements

The device used to record FVC and FEV_1 should provide at least a tracing of volume-time or volume-flow during the entire forced expiration. For the volume-time tracing the recorder must be capable of displaying the entire FVC maneuver, at a constant speed, from maximum inspiration for at least 10 seconds after the start of the maneuver. (The tracing must be stored and available for recall.) If a paper record is made it must have at least the following characteristics: Paper speed, at least 2 cm per sec; higher speeds are preferred. Volume sensitivity, at least 10.0 mm of chart per liter of volume. (BTPS) Flow sensitivity, at least 4.0 mm of chart per liter per sec of flow (BTP).

Rationale

Spirograms still represent the best method of ensuring that this "effort-dependent" test is properly performed. Most forced vital capacity spirometric analysis is made from a volume-time tracing; to determine the quality of the start of the FVC test and achieve reliable results by back extrapolation to determine time zero, the recorder should be up to speed before forced expiration is begun. (See figure 1 and associated discussion below). The ten second record requirement is based on the data presented earlier (2) and shown in Appendix A table 4. The requirements for chart speed and volume sensitivity are based on earlier recommendations (9, 24) and the need to have adequate visual resolution on the record. Whatever methods are used, techniques need to be developed that (*1*) minimize patient time, (2) minimize technician effort and cost, (*3*) provide for comparison and consistency between laboratories, and (*4*) do not throw away important information.

Standards for Forced Vital Capacity Measurement

Instrumentation

Diagnostic spirometry should be performed with a spirometer that meets the technical specifications of the American Thoracic Society as outlined above. Workshop participants agreed that the spirometer specifications should apply to *all diagnostic spirometers* whether used for clinical, diagnostic, or epidemiologic purposes.

Rationale

Instrumentation standards should be met to provide accurate spirometric data and information that is comparable from laboratory to laboratory and from one time period to another.

Standard Methods for Test Perfcrmance

Subjects will be instructed in the FVC maneuver, and the appropriate technique will be demonstrated. A minimum of 3 acceptable FVC maneuvers will be performed. Acceptability will be determined by the technician's observation that the subject understood the instructions and performed the test with a smooth continuous exhalation, with apparent maximal effort, with a good start, and without (*1*) Coughing, (2) Valsalva maneuver (glottis closure). (*3*) Early termination of expiration. (In a normal patient this would be before completion of the breath; in an obstructed patient this would be assumed to have taken place if the expiratory time was less than 5 sec.) (*4*) A leak. (*5*) An obstructed mouthpiece (obstruction due to the tongue being placed in front of the mouthpiece, false teeth falling in front of the mouthpiece, etc.). (*6*) An unsatisfactory start of expiration, characterized by excessive hesitation or false starts. Unsatisfactory starts prevent accurate back extrapolation and determination of time zero. To achieve accurate time zero the extrapolated volume on the volume time tracing-spirogram—should be less than 10 per cent of the FVC or 100 ml whichever is greater. (See figure 1 for definition of extrapolated volume). (7) An excessive variability among the 3 acceptable curves. The 2 best of the 3 acceptable curves should not vary by more than ± 5 per cent of reading or ± 100 ml, whichever is greater.

Rationale

At least 3 acceptable tests are required to ensure that maximal effort and cooperation are obtained

and that the tests provide an accurate reflection of the subject's pulmonary function. This conclusion was achieved after reviewing the data of Knudson and associates (Appendix B, table 1) (20) and others (7, 21). There is no need to obtain more than 3 acceptable tests.

Nose Clips

Nose clips are recommended but not required.

Rationale

Although the use of nose clips does not appreciably influence the FVC performed using the open circuit technique, some subjects breathe through the nose during testing when a closed circuit technique is used. However, it was agreed that although nose clips are recommended, they are not required to maintain a standard method of testing.

Sitting versus Standing

Adult subjects may be studied in the sitting or standing position. No indication of position is necessary. In children under the age of 12, the position should be indicated.

Rationale

Pierson and co-workers (22) indicate that no clinically significant differences exist between spirometric data from sitting and standing subjects. Unpublished data (R. Lemen) indicate that in children, VC is greater in the standing than in the sitting position.

Measurement

Spirometric variables should be measured from a series of at least 3 acceptable forced expiratory curves. The maximal FVC and the maximal FEV_1 (BTPS) will be recorded, after examining the data from all of the acceptable curves, even if the two values do not come from the same curve. If the $FEF_{25-75\%}$ and/or the instantaneous maximum expiratory flows ($\dot{V}$) are obtained from a single test, the test used will be the one with the greatest sum of FEV_1 and FVC (7).

Rationale

Best efforts cannot be determined by simple inspection of a spirogram. Measurements and calculation are required to determine the largest values. There is rarely a significant difference between the largest values and the mean values in normal subjects. However, independently selecting the largest value for FVC and FEV_1 accounts for the occasional influence of learning and possible deterioration in performance due to fatigue or induced bronchospasm. There is no need to discard the best FEV_1 even if the maneuver is prematurely terminated. $FEF_{25-75\%}$ will be influenced by the FVC of the curve from which it is determined. Spuriously high values may be reported if obtained from maneuvers with lower FVC. Summing the $FEV_1$and FVC provides an objective and simple method of defining the "best" curve (7).

Clinical/Epidemiologic Considerations

The issue of clinical versus epidemiologic considerations for test selection and test recording was discussed. There were major agreements but some minor disagreements about test selection and when and how testing should be averaged. In the vast majority of the cases the instrument requirements, testing procedures, and numbers of tests required were agreed to by both the clinical and the epidemiologic participants.

Technician Training

The critical importance of training of pulmonary technicians was discussed at length. It was decided that it is best to provide proper supervision and not certification. Cost factors mitigate against certification, which of itself does not ensure quality. It was recommended that ALA/ATS follow up on development of training criteria and call upon lung associations and chapters to identify qualified and accessible training sites. A related concern is that many physicians supervising pulmonary function laboratories in community hospitals are not adequately prepared. These needs should be included as a consideration in the ALA/ATS hospital consultation program. It was almost unanimously agreed that the manufacturers are not providing proper training in the use of spirometric equipment and that the need for hands-on live patient capabilities was of crucial importance in training. Therefore, in the foreseeable future the workshop did not expect that manufacturers would be able to meet training needs.

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APPENDIX B

KNUDSON, R.J., SLATEN, R.C., LEBOWITZ, M.D., AND BURROWS, B.: THE MAXIMAL EXPIRATORY FLOW VOLUME CURVE. NORMAL STANDARDS, VARIABILITY, AND EFFECTS OF AGE, AM REV RESPIR DIS, 1976, *113*, 871

TABLE 1

COMPARISON OF THE BEST OF THE FIRST 3 WITH THE BEST OF 5 TESTS (APPROXIMATELY 3,000 PEOPLE)

	Year 1	Year 2
They were identical in:	63.1%	67%
They were within 5% of each other in:	90.1%	93.9%
Thus, the best occurred in the last 2 in: (*but in only 25% were differences greater than 25 ml)	37%*	33%
When the best FEV_1 occurred in the last 2 tests, it was at least 5% greater than the best of the first 3 in:	9.9%	6.1%
When the best FEV_1 occurred in the last 2 tests, it was at least 10% greater than the best of the first 3 in:	2.7%	1.7%